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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/625,963	07/26/00	STAUSS H	ICI 101

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EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/625,963	Strauss et al.
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication app ars on the cover sheet with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 5-20, and 22-38* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1, 5-20, and 22-38* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. A restriction is required under 35 USC 121 between (one of the following groups):

I. Claims 1, 4-7, 15 and 19, drawn to the embodiment of a peptide comprising the amino acid sequence of SEQ ID NO:1, or a portion or variant thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 300, and class 514, subclass 15,

II. Claims 1, 4-6, 8, 15 and 19, drawn to the embodiment of a peptide comprising the amino acid sequence of SEQ ID NO:2, or a portion or variant thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 300, and class 514, subclass 15,

III. Claims 1, 4-6, 9, 15 and 19, drawn to the embodiment of a peptide comprising the amino acid sequence of SEQ ID NO:3, or a portion or variant thereof, and pharmaceutical composition thereof, classified in Class 530, subclass 300, and class 514, subclass 15,

IV. Claims 10-14, 16 and 19, drawn to the embodiment of a polynucleotide encoding a peptide comprising the amino acid sequence of SEQ. ID NO:1, or a portion or variant thereof, a host cell and an expression vector capable of expressing said peptide, a method of producing said peptide and a pharmaceutical composition comprising said polynucleotide, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 252.3, 320.1, and Class 514, subclass 44,

V. Claims 10-14, 16 and 19, drawn to the embodiment of a polynucleotide encoding a peptide comprising the amino acid sequence of SEQ ID NO:2, or a portion or variant thereof a host cell and an expression vector capable of expressing said peptide, a method of producing said peptide and a pharmaceutical composition comprising said polynucleotide, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 252.3, 320.1, and Class 514, subclass 44,

VI Claims 10-14, 16 and 19, drawn to the embodiment of a polynucleotide encoding a peptide comprising the amino acid sequence of SEQ ID NO:1, or a portion or variant thereof a host cell and an expression vector capable of expressing said peptide, a method of producing said peptide and a pharmaceutical composition comprising said polynucleotide, classified in Class 536, subclass 23.1, Class 435,

subclasses 69.1, 252.3, 320.1, and Class 514, subclass 44,

VII Claims 17, 20 and 36-37 drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering a peptide of SEQ ID NO:1, classified in Class 424, subclass 154.1,

VIII Claims 18, 20 and 36-37, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering a polynucleotide encoding or expressing the peptide of SEQ ID NO:1, classified in Class 514, subclass 44,

IX Claims 17, 20 and 36-37, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering a peptide of SEQ ID NO:2, classified in Class 424, subclass 154.1,

X. Claims 18, 20 and 36-37, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering a polynucleotide encoding or expressing the peptide of SEQ ID NO:2, classified in Class 514, subclass 44,

XI Claims 17, 20, 36 and 38, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering a peptide of SEQ ID NO:3, classified in Class 424, subclass 154.1,

XII Claims 18, 20, 36 and 38, drawn to a method of killing target cells in a patient that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering a polynucleotide encoding or expressing the peptide of SEQ ID NO:3, classified in Class 514, subclass 44,

XIII Claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes in vitro comprising contacting cells with an antigen of a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in Class 435, subclass 7.2,

XIV Claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes in vitro comprising contacting cells with an antigen of a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in Class 435, subclass 7.2,

XV. Claims 22-27, drawn to a method of producing activated cytotoxic T lymphocytes in vitro comprising contacting cells with an antigen of a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in Class 435, subclass 7.2,

XVI Claims 28-29, drawn to activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:1, classified in class 435, subclass 325,

XVII Claims 28-29, drawn to activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of

SEQ ID NO:2, classified in class 435, subclass 325,

XVIII Claims 28-29, drawn to activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:3, classified in class 435, subclass 325,

XIX. Claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in Class 530, subclass 350,

XX. Claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in Class 530, subclass 350,

XXI. Claim 30, drawn to a T cell receptor which recognizes a cell which aberrantly expresses a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in Class 530, subclass 350,

XXII Claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberantly expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in Class 536, subclass 23.5,

XXIII Claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberantly expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:2, classified in Class 536, subclass 23.5,

XXIV Claims 31-32, drawn to a polynucleotide encoding a T cell receptor which recognizes a cell aberantly expressing a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in Class 536, subclass 23.5,

XXV Claims 33-34, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:1,

XXVI Claims 33-34, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:2,

XXVII Claims 33-34, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:3

XXVIII Claim 35, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1 comprising administering dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:1

XXIX Claim 35 drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:2 comprising administering dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:2,

XXX Claim 35, drawn to a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:3 comprising administering comprising administering dendritic cells that have been contacted with a peptide comprising the amino acid sequence of SEQ ID NO:3

Note: Any claims listed above in multiple groups will only be examined for the embodiment of the group elected.

The inventions are distinct, each from the other because:

4. Inventions I-III and VII/IX/XI, respectively, Inventions IV-VI and XIII/X/XII, respectively, Inventions XVI-XVIII and XXV-XXVII, respectively, and Inventions I-III and XXVIII-XXX, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the peptide products encompassed by Inventions I-III, can be used as an antigen for the production of antibodies, as well as in a method of killing target cells in a patient as encompassed by Inventions VII/IX/XI and Inventions XXVIII-XXX.

In the instant case, the nucleotide product encompassed by Inventions IV-VI can be used in a process of making a DNA vaccine, as well as in a method of killing target cells in a patient, as encompassed by Inventions XIII/X/XII

In the instant case, the activated cytotoxic T lymphocytes which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:1, product as encompassed by Inventions XVI-XVIII, can be used in a materially different process such as screening for peptide analogues able to be recognized by said CTLs, as well as in a method of killing target cells, that aberrantly express a polypeptide comprising the amino acid sequence of SEQ ID NO:1, 2 or 3, comprising administering CTL which recognize a cell which aberrantly expresses a polypeptide comprising an amino acid sequence of SEQ ID NO:1, 2 or 3 , as encompassed by Inventions XXV-XXVII.

5. Groups XIII-XV and XVI-XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the activated CTL can be

made in vivo by immunizing a mammal with a peptide comprising the amino acid sequence of SEQ ID NO:1, 2 or 3.

6. Inventions VII-XII, XXV-XXVII and XXVIII-XXX, and Inventions XIII-XV are distinct methods because they have different endpoints; methods of killing target cells in a patient, and methods of producing activated cytotoxic T lymphocytes in vitro, respectively. Though the methods of Inventions VII/IX/XI, VII/X/XII, XXV-XXVII and XXVIII-XXX have the same endpoints, said methods are distinct because the endpoints are achieved by administering different components; a peptide, a polynucleotide, CTL or dendritic cells, respectively.

Inventions VII/IX/XI are each a patentably distinct method because each of said inventions comprises the administration of a peptide with a unique sequence; SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3, respectively. Inventions VIII/X/XII are each a patentably distinct method because each of said inventions comprises the administration of a polynucleotide that encodes a peptide with a unique sequence; SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3, respectively. Inventions XXV-XXVII are each a patentably distinct method because each of said inventions comprises the administration of CTL which recognize a cell which aberrantly expresses a polypeptide comprising a unique sequence; SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3, respectively. Inventions XXVIII-XXX are each a patentably distinct method because each of said inventions comprises the administration of dendritic cells which have been contacted with a polypeptide comprising a unique sequence; SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3, respectively. Inventions XIII-XV are each a patentably distinct method because each of said inventions comprises a method of producing activated cytotoxic T lymphocytes in vitro comprising contacting cells with an antigen of a polypeptide comprising a unique sequence; SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3, respectively. Therefore, Inventions VII-XII, XXV-XXVII and XXVIII-XXX, and Inventions XIII-XV are patentably distinct.

7. Inventions I-III, IV-VI, XVI-XVIII, XIX-XXI and XXII-XXIV are different products, encompassing peptides each with a distinct sequence, nucleic acids each with a distinct sequence, CTLs each directed to a peptide with a distinct sequence, TCRs each which recognizes a peptide with a distinct sequence, and nucleic acid molecules, each encoding TCRs which recognize different cells, wherein each cel aberantly expresses a peptide with a distinct sequence. Nucleic acids, polypeptides, CTLs and TCRs are distinct because their structures and modes of action are different, which require non-coextensive searches. Therefore, they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is reminded that upon the cancellation of claims to a non-elected

invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
May 18, 2001

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